

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 50821/5 PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/35162	International filing date (day/month/year) 04 November 2003 (04.11.2003)	Priority date (day/month/year) 04 November 2002 (04.11.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/505; C07D 403/10, 239/91. and US Cl.: 514/264.1, 266.2, 266.3; 544/279, 287.			
Applicant NPS PHARMACEUTICALS, INC.			

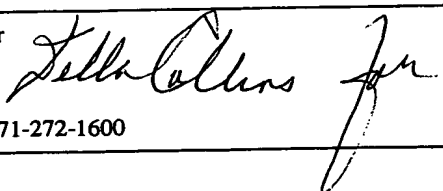
1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21 June 2004 (21.06.2004)	Date of completion of this report 19 March 2005 (19.03.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer James O Wilson  Telephone No. 571-272-1600

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/35162

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:

pages 1-67 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

☒ the claims:

pages 68-72 as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

☒ the drawings:

pages 1 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>10 and 14-19</u>	YES
	Claims <u>1-9, 11-13</u>	NO
Inventive Step (IS)	Claims <u>10 and 14-19</u>	YES
	Claims <u>1-9, 11-13</u>	NO
Industrial Applicability (IA)	Claims <u>1-19</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Claims 1-9, 11-13 lack novelty under PCT Article 33(2) as being anticipated by **Venkatesan et. al.** (US 5,290,780 A). The compounds in Table VI (column 30 of US'780) anticipate compounds recited in the instant claims 1-9, 11 and 12. The pharmaceutical composition taught in US'780 also anticipates the instant claim 13, which has been inadvertently overlooked in the Search Report.

Claims 1-9, and 13 also lack novelty under PCT Article 33(2) as being anticipated by the following references:

Jones et. al. (US 5,236,927 A): The compound on the first line of column 10 (US'927) anticipates compounds recited in the instant claims 1-9 as well as the pharmaceutical composition recited in the instant claim 13.

Allen et. al. (US 5,240,928 A): The compounds in Example 88 (column 75 of US'928) anticipate compounds recited in the instant claims 1-9 as well as the pharmaceutical composition recited in the instant claim 13.

Chakravarty et. al. (US 5,162,325 A): Compounds #23 and 25 (column 56 of US'325) anticipate compounds recited in the instant claims 1-9 as well as the pharmaceutical composition recited in the instant claim 13.

Merck & Co., INC. NC. (EP 411,766 A1): Compound (i) on page 15 (of EP'766)

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

anticipates compounds recited in the instant claims 1-9 as well as the pharmaceutical composition recited in the instant claim 13.

Takeda Chemical Industries (EP 445,811 A2): Compounds in Table 7a on page 43 (of EP'811) anticipate compounds recited in the instant claims 1-9 as well as the pharmaceutical composition recited in the instant claim 13.

Claims 1, 11 and 13 also lack novelty under PCT Article 33(2) as being anticipated by **de Laszlo et. al.** (US 5,385,894). The compound on line 58 of column 40 anticipates compounds recited in the instant claims 1 and 11 as well as the pharmaceutical composition recited in the instant claim 13.

Claims 1-9, and 11-13 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraphs.

Claims 10 and 14-19 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the compounds as recited in the instant claim 10, their methods of use, and process of making recited in the instant claims 14-19.

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus they have industrial applicability because the subject matter claimed can be made or used in the pharmaceutical industry.